REMARKS

Applicants acknowledge and thank the Examiner for withdrawing the 102 rejection based on *Chopdekar et al.* (U.S. 5,663,415). Applicants note that the Examiner did not comment on *Leflein et al.* (U.S. 6,417,206). Accordingly, it appears that the 102 rejection was not maintained with regard to *Leflein et al.*, thus, Applicants assume this reference has also been overcome.

Applicants also note that claims 1-16 are provisionally rejected on the ground of nonstatuatory double patenting over claims 1, 3-6, 31-35 and 39 of copending Application No. 10/047,578. Application No. 10/047,578 claims an invention that was commonly owned with the present invention at the time the invention was made and was a result of activities undertaken within the scope of a joint research agreement. Applicants will file a Terminal Disclaimer to overcome the provisional rejection based on the nonstatuatory double patenting ground once patentable subject matter has been determined.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by *Gordziel* (U.S. 6,037,358 – the '358 patent), for the reasons set forth in the Office Action mailed on November 1, 2006.

Turning now to the 102 rejection as maintained with regard to *Gordziel*, the Examiner indicates that "With respect to the instantly claimed steps of combining the tannate salt complex of the active ingredient without isolation or purification … the patentabililty of the product is not dependent upon the manner in which [*sic*] is produced unless the process changes the product (emphasis added)."

Applicants would like to direct the Examiner to the "Summary of the Invention" on page 3, lines 11-14 of the specification which states, "removing the necessity of an additional isolation step, the invention provides a reproducible method to manufacture liquid or semi-liquid products containing tannate salt complexes as active ingredients with decreased variability in dose."

Submitted herewith as Appendix I are two Declarations Under 37 C.F.R. 1.132 from a related patent application (now U.S. Patent No. 6,869,618) which relate to the very issue raised by the Examiner, i.e., the patentability of the product not being dependent upon the manner in which it is produced unless the process changes the product. While the attached Declarations relate to U.S. Patent No. 5,663,415 (the '415 patent), it should be noted that the '415 patent refers to the *Gordziel* patent as an alternate route. Both the '415 patent and the *Gordziel* patent utilize additional isolation and purification steps which increase the content variability of the active ingredient in the finished pharmaceutical product.

Gordziel, in the '358 patent, discloses the preparation of tannate salts by reacting the free base, e.g., phenylephrine, chlorpheniramine, etc. with tannic acid in the presence of a volatile solvent, which is cooled to room temperature and then filtered, washed with isopropanol and then vacuum dried (see column 1, lines 65-67 and column 2, lines 6-8). The '358 patent further states that alternative routes to the tannate salts are described in U.S. Patent No. 5,599,846 and the '415 patent.

While the attached Declarations relate to the '415 patent, as indicated above, the '415 patent refers to the '358 patent as an alternate route for preparing tannate salts of pharmaceutically active ingredients. Both the '415 and '358 patents utilize additional

isolation and purification steps which increase the content variability of the active ingredient in the finished pharmaceutical product.

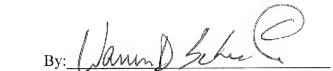
Referring specifically to the attached Declaration of Jeffrey S. Kiel, Applicants would like to direct the Examiner to paragraph 8 wherein Dr. Kiel emphasizes that the additional isolation step set forth in the '415 patent actually increases the content variability of the active ingredient that is processed into finished pharmaceutical product. The data set forth in Tables 1, 2 and 3 demonstrate that pharmaceutical products produced using methods which utilize isolated tannate salts of variable content as described in the '415 patent will inherently have more variation in the amount of active ingredient they contain than will those pharmaceutical products produced using the presently claimed Kiel method. Further in paragraph 13, Dr. Kiel indicates that by eliminating the additional isolation step required by the prior art, a potential source of increased content variability is eliminated. Referring to paragraph 14, decreased content variability produces a much safer drug. The Declaration under 37 C.F.R. 1.132 of Timothy R. Flynn, M.D. is submitted to support the potential danger to patients by administering dosage forms that have variable amounts of active ingredient. All of the above statements made by Drs. Kiel and Flynn are applicable to the '358 patent and the present application.

Independent claims 1, 5 and 16 (as amended), all contain the phrase "without isolation or purification" when referring to the process of forming a finished therapeutic dosage form from the newly generated tannate salt complex of the active pharmaceutical ingredient. Thus, the rejection of the present application under 102 based on *Gordziel* (the '358 patent) cannot be maintained.

Based on the above, it has been demonstrated that claims 1-16 are patentable over the prior art and in condition for allowance. Such action is earnestly requested. The Examiner is encouraged to contact the undersigned below should he have any questions.

Respectfully submitted,

KING & SCHICKLI, PLLC

By: 

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